246 EUR-1008 (a new pancraetic enzyme product, PEP) was shown to be safe and effective in cystic fibrosis (CF) patients with exocrine pancreatic insufficiency (EPI)

J.E. Heubi[1], S.R. Boas[2], K. Blake[3], S.Z. Nasr[4], M.S. Woo[5], G.R. Graff[6], K.A. Hardy[7], R. Amaro-Galvez[8], M. Latino[9], C. Lee[10]. *[1]Children's Hospital, Cincinnati, OH, USA; [2]Chicago CF Care, Glenview, IL, USA; [3]Nemours, Jacksonville, FL, USA; [4]Michigan University, Ann Arbor, MI, USA; [5]Children's Hospital, Los Angeles, CA, USA; [6]Penn State Hospital, Hersey, PA, USA; [7]Children's Hospital, Oakland, CA, USA; [8]Texas University, Tyler, TX, USA; [9]Eurand spa, Milano, Italy; [10]Eurand Inc, Vandalia, OH, USA*

The objective of the study was to evaluate the efficacy and safety of EUR-1008 for the treatment of malabsorption in CF patients with EPI.

Study design: This multicenter, double blind, crossover, placebo-controlled trial was performed at 14 US sites. The main study efficacy endpoint was the comparison of the coefficient of fat absorption (CFA) during treatment with EUR-1008 vs. placebo. Secondary endpoints included comparison of the coefficient of nitrogen absorption (CNA), incidence of clinical symptoms of EPI, blood levels of cholesterol, triglycerides and fat soluble vitamins. The safety endpoints included the assessment of adverse events, clinical laboratory parameters, physical examination findings and vital sign measurements.

Results: Thirty-four patients (17F, aged 7–23/17M, aged 7–24) were enrolled with 31 patients completing all the phases of the study. Three patients discontinued but none for treatment-related reasons. No drug-related serious adverse events were reported. The CFA and CNA significantly increased ($p < 0.001$) following treatment with EUR-1008 vs placebo (88.28% vs 62.76% and 87.17% vs 65.67%, respectively).

Cholesterol and vitamin K levels increased and symptoms of malabsorption were controlled after treatment with EUR-1008.

Conclusion: In a randomized, double blind, placebo-controlled study, EUR-1008 was shown to be effective, safe and well tolerated for the treatment of EPI in CF patients.